# ORAL COMPOSITIONS PROVIDING ENHANCED OVERALL CLEANING

## CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit under 35 USC 119(e) to U.S. Application Serial No. 60/323,304 filed Sep. 19, 2001.

## FIELD OF THE INVENTION

Disclosed are oral compositions and methods for enhanced overall cleaning, whitening, stain removal and preventing of staining of natural teeth and dental prosthesis. In particular, these benefits are achieved by applying to the teeth compositions comprising in an orally acceptable carrier a copolymer comprised of vinyl pyrrolidone (VP) and alkenyl carboxylate (AC) monomers.

## BACKGROUND OF THE INVENTION

The formation of dental plaque and calculus is the primary source of dental caries, gingivitis, periodontal disease, and tooth loss. Dental plaque is a mixed matrix of bacteria, epithelial cells, leukocytes, macrophages and other oral exudate. Bacteria comprise approximately three-quarters of the plaque matrix. Any given sample of dental plaque could contain as many as 400 different varieties of microorganisms. This mix includes both aerobic and anaerobic bacteria, fungi, and protozoa. Viruses have also been found in samples of dental plaque.

This matrix of organisms and oral exudate continues expanding and coalesces with other plaque growths situated nearby. The bacteria synthesize levans and glucans from sucrose found in the oral cavity providing energy for the microorganisms. These glucans, levans, and microorganisms form an adhesive skeleton for the continued proliferation of plaque.

Dental calculus, or tartar as it is sometimes called, is a deposit which forms on the surfaces of the teeth at the gingival margin. Supragingival calculus appears principally in the areas near the orifices of the salivary ducts; e.g., on the lingual surfaces of the lower anterior teeth and on the buccal surfaces of the upper first and second molars, and on the distal surfaces of the posterior molars. Mature calculus consists of an inorganic portion which is largely calcium phosphate arranged in a hydroxyapatite crystal lattice structure similar to bone, enamel and dentine. An organic portion is also present and consists of desquamated epithelial cells, leukocytes, salivary sediment, food debris and various types of unless stained or discolored by some extraneous agent. In addition to being unsightly and undesirable from an aesthetic standpoint, the mature calculus deposits are constant sources of irritation of the gingiva.

The failure to retard or stop the proliferation of plaque and calculus is detrimental to oral health. Plaque and calculus formation may lead to dental caries, gingival inflammation, periodontal disease, and ultimately tooth loss. Additionally, calculus and plaque along with behavioral and environmental factors lead to formation of dental stains, significantly affecting the aesthetic appearance of teeth. Behavioral and environmental factors that contribute to teeth staining propensity include regular use of coffee, tea, cola or tobacco products, and also the use of stain promoting oral products, such as chlorhexidine.

The ultimate oral cleaning level is what dentists provide during prophylaxis; daily oral care at home requires products with multiple ingredients working by different mechanisms to provide satisfactory cleaning and whitening. Thus, for oral care products for daily use such as dentifrice and rinses to provide overall cleaning, it is necessary to add ingredients for provision of antiplaque and anticalculus benefits as well as stain removal, stain control and tooth whitening. Such ingredients for removal and control of stain and for whitening include bleaches, abrasives or chemical chelants. Bleaches added to dentifrices are typically present in low concentrations due to stability and safety limits unique to toothpastes. At these low concentrations, bleaches which are typically oxidizing agents, are generally ineffective at tooth whitening and stain control. Dental abrasives provide important whitening benefits, particularly on 'brushed' areas of teeth, but unfortunately are of limited effect in controlling aesthetically undesirable stains that form along the gumline and interproximally. Bleaches and abrasives do not functionally act to prevent acquisition of stains. Abrasive use can reduce rates of stain acquisition by daily removal of newly acquired stains, but this action is a 'treatment' for existing stain, not a preventive chemical action.

Chemical chelants have been suggested in the art to retard calculus formation and to remove calculus after it is formed. The chemical approach to calculus inhibition generally involves chelation of calcium ion and/or crystal growth inhibition which prevents the calculus from forming and/or breaks down mature calculus by removing calcium. In addition, chemical chelants can in principle remove stains by binding to teeth surfaces thereby displacing color bodies or chromagens. The retention of these chelants can also prevent stains from accruing due to disruption of binding sites of color bodies on tooth surfaces.

A number of agents with chelating properties for use in controlling plaque, calculus and stain have been disclosed in the art. For example, ethylenediaminetetraacetic acid, nitrilotriacetic acid and related compounds are disclosed in British Patent 490,384, Feb. 15, 1937; polyphosphonates in U.S. Pat. No. 3,678,154, Jul. 18, 1972 to Widder et al., U.S. Pat. No. 5,338,537 issued to Aug. 16, 1994 to White, Jr., and U.S. Pat. No. 5,451,401 issued Sep. 19, 1995 to Zerby et al.; carbonyl diphosphonates in U.S. Pat. No. 3,737,533, Jun. 5, 1973 to Francis; a zinc-polymer combination formed by the reaction or interaction of a zinc compound with an anionic polymer containing carboxylic, sulfonic and/or phosphonic acid radicals in U.S. Pat. No. 4,138,477, issued Feb. 6, 1979, to Gaffar; tartaric acid in U.S. Pat. No. 5,849,271 issued Dec. 15, 1998 and U.S. Pat. No. 5,622,689 issued Apr. 22, 1997 both to Lukacovic; acid or salt form of tartrate monosuccinate, tartrate disuccinate, and mixtures thereof in U.S. Pat. No. 5,015,467 issued May 14, 1991 to Smitherman; acrylic acid polymer or copolymer in U.S. Pat. No. 4,847,070, Jul. 11, 1989 to Pyrz et al. and in U.S. Pat. No. 4,661,341, Apr. 28, 1987 to Benedict et al.; sodium alginate in U.S. Pat. No. 4,775,525, issued Oct. 4, 1988, to Pera; polyvinyl pyrrolidone in GB 741,315 published Nov. 30, 1955, WO 99/12517 published Mar. 18, 1999 and U.S. Pat. No. 5,538,714 issued Jul. 23, 1996 to Pink et al.; and copolymers of vinyl pyrrolidone with carboxylates in U.S. Pat. No. 5,670,138 issued Sep. 23, 1997 to Venema et al. and in JP Publication No. 2000-0633250 to Lion Corporation, published Feb. 29, 2000.

Dentrifrices and mouthwashes containing soluble pyrophosphate salts have also been disclosed in the art, the pyrophosphates being indicated for a variety of purposes including as anticalculus agent. Included among such disclosures are U.S. Pat. No. 2,941,926, Jun. 21, 1960 to